DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-03-2010 has been entered.

2. Claims 1-3, 6, 8-15, 17-19, 21, 23-28, 63-66, 68, 70-76, and 85-95 are presently pending for examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

4. The rejection of claim 9 as set forth in the prior Office Action, under 35 U.S.C. 112, second paragraph, is withdrawn.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 6, 8-15, 17-19, 21, 23-28, 63-66, 68, 70-76, and 85-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1, 15, 24-28, 63-64 and 85-86 and those claims dependent therefrom recite the phrase an “effective amount of pulsed radiofrequency..” This term is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See for example claims 71-76, wherein the effective amount of pulsed radiofrequency is sufficient to: activate a signal transduction protein, activate a cell cycle regulator, activate a transcription factor, activate a DNA synthesis protein, activate a receptor, and to inhibit an Angiotensin Receptor. It is clear that the term "effective amount," as recited in these claims would be expected to vary depending upon the application. However, there is no clear standard for determining the "effective amount."

8. Claim 8 recites: “[T]he method of claim 1, wherein said cell is selected from the group consisting of fibroblast, neuronal cell, epithelial cell, macrophage, neutrophil, endothelial cell, skeletal muscle cell, smooth muscle cell, chondrocyte, and bronchial cell.” However, the cell of claim 1 is part of a gastrointestinal tissue or lung tissue. There is no antecedent basis for the full scope of claim 8 in claim 1, specifically for the limitations neuronal cell, macrophage, neutrophil, skeletal muscle, and chondrocyte.

Claim Rejections - 35 USC § 102

9. The rejection of claims 8, 23, and 70 under 35 U.S.C. 102(b) as being anticipated by Gordon (US 4758429), is withdrawn in response to Applicant’s amendment and arguments.

10. The rejection of claims 1-3, 5-15, 17-28, 63-76 and 85-86 under 35 U.S.C. 102(a or e) as being anticipated by Ganz et al. (US 6491618; see entire disclosure of reference), is withdrawn in response to Applicant's amendment.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-3, 6, 8-15, 17-19, 21, 23-28, 63-66, 68, 70-76, and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over George et al. (US Patent No. 6353763; see entire document).

13. Claim 1 recites: "[A] method for accelerating the cell cycle of a cell, comprising delivering to a cell an effective amount of electromagnetic energy pulsed radiofrequency radiation, wherein said cell is part of a gastrointestinal tissue or lung tissue wherein said pulsed radiofrequency radiation accelerates the cell cycle of said cell by at least 2-fold, and wherein the cell being treated does not sustain substantial DNA damage."

14. George et al. teach a method which utilizes electromagnetic energy as a mitogenic stimulus to reduce cell cycle time through the expression, synthesis and enhanced activity of growth factors, thereby increasing the overall rate of growth and proliferation in various biological cell types, including those found in epithelial, muscle, connective and neuronal tissues. Fibroblasts and endothelial cells are also listed, see Example 4. Energy waves which are primarily defined as Radio Wave frequencies are used to induce biological cell proliferation in vitro under laboratory conditions and in vivo

under clinical conditions in intact living organisms. In the electromagnetic spectrum, those frequencies range from 1000 Hertz to 1000 Megahertz, and therefore also include a portion of the audio frequencies (at the lower end) and range through ultra-high frequencies (UHF). The present method delivers electromagnetic treatment energy of 1 to 300 mW/cm^2 to living tissues (in vivo or in vitro). Because it is a specific cellular mitogen, the present method reduces cell cycle time through the induction of specific cellular mechanisms which reduce the duration of the separate and/or combined G_0 and G_1 phases of the cell cycle. Specific mitogenic physical energy signals are provided that induce cell growth and proliferation in part through the induction of ion flux across cellular membranes and subsequent cellular signaling events, including the expression, synthesis and enhanced activity growth factors, especially fibroblast growth factors. An electromagnetic energy stimulus is utilized to activate intracellular and intercellular mechanisms associated with the genetic expression, synthesis and release of biological molecules necessary to regulate cell cycle time. (see Col. 9) Moreover, "[T]reatments applied using the present method are characterized by specific optimal dosages of pulsed electromagnetic energy to induce cell proliferation of specific cell types." (see Col. 10)

15. Since the teachings of George et al. discloses the method step of the claimed invention, which comprises delivering electromagnetic radiation (including light, x-ray, radiofrequency radiation, infrared, microwave and ultraviolet radiation) into a body cavity of a patient, including the gastrointestinal tract and lungs, absent evidence to the contrary the ordinary skilled artisan would also expect that the prior art method would also produce the further function of accelerating the cell cycle, activating a cell cycle

regulator, activating a signal transduction protein, activating a transcription factor, a DNA synthesis protein, a receptor and inhibiting an angiotensin receptor of the cells exposed to the radiant energy.

16. Moreover, the recitation of the limitations "for" accelerating the cell cycle, activating a cell cycle regulator, activating a signal transduction protein, activating a transcription factor, a DNA synthesis protein, a receptor and inhibiting an angiotensin receptor, recited in the preamble of the instant claims are interpreted as intended use limitations. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

17. Furthermore, it is noted that George et al. does not specifically teach accelerating the cell cycle of a cell that is part of a gastrointestinal tissue or lung tissue. However, absent evidence to the contrary, since the methods of George et al. target cells that are considered part of a gastrointestinal tissue or lung tissue, the ordinary skilled artisan would have been motivated and would have had a reasonable expectation of success in targeting these tissues.

18. Moreover, George et al. does not specifically teach that their disclosed method results in at least 2-fold cell cycle increase. Absent evidence to the contrary, as per MPEP § 2144.05 [R-5] "[W]here the general conditions of a claim are disclosed in the

prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

19. Regarding the limitation wherein "the cell being treated does not sustain substantial DNA damage," George et al. clearly teaches the use of pulsed electromagnetic energy, including RF, which is in the range of 1 to 300 mW/cm2 to living tissues. Absent evidence to the contrary, the methods of George et al. would not sustain substantial DNA damage since it is performed within the same range recited in the instant claims.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633